

1651 Market Street #303
San Francisco, Ca. 94103
415-864-0738
henryruhe@aol.com
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Division of Dockets Management
FDA
5630 Fishers Lane, Room 1061(HFA-305)
Rockville, MD 20852-0003

Re: Citizens Petition to Compel Enforcement of Amyl Nitrite in re 21 CFR 250.100
FDA Docket #2004P-0411/CP 1 filed September 9 2004

Dr. Lester Crawford, FDA Commissioner:

Enclosed are supporting research articles and supporting declaration dated October 14, 2004. The enclosed articles are numbered to correspond with the reference listings. These submissions are in addition to previously submitted supporting documents #1-107.

Risk factor for unsafe sex:

108. Fernandez, MI, et al., 2004, November. The internet as recruitment tool for HIV studies and strategy for reaching at-risk Hispanic MSM in Miami. AIDS Care 16(8): 953-963.

109. Hirshfield, S. et al., 2004 November. Substance use and high-risk sex among men who sex with men: a national online study in the USA. AIDS Care 16(8): 1036-47.

110. Paul, Jay et al., 1993. Sexual risk for HIV transmission among gay/bisexual men in substance-abuse treatment. AIDS Education and Prevention 5(1) 11-24.

111. McKirnan, D. et al., 1993. Predictors of unsafe sex among bisexual men: the role of gay identification. Abstract PO-/d07-3607 at Int'l AIDS Conference in Berlin.

112. Willoughby, B. et al., 1991. characteristics of risk takers among seronegative men in a gay cohort. Abstract W.C.3003 at Int'l AIDS Conference in Florence.

113. Klotz, D. et al., 1991. Correlation of drug taking and high risk sexual behavior in 774 gay men in New York City: Implications for prevention. Abstract W.C.3009 at Int'l AIDS Conference in Florence.

114. Calzavarra. Livianna et al., 1990. Recreational drug use during sexual activity and high-risk sexual behaviour in the Toronto sexual contact study. Rejected Abstract #1181. Sixth International Conference on AIDS, San Francisco.

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Seroconversion risk factor

115. Newell, Guy et al., Risk factor analysis among men referred for possible Acquired Immune Deficiency Syndrome. 1985. Preventive Medicine 14: 81-91.

Immunosuppression risk factor

116. Fallon, Theodore et al., 1986. Telangiectasias of anterior chest in homosexual men. Annals of Internal Medicine 105: 679-682.
117. Soderberg, Lee et al., 2002. Cytotoxicity by nitrite inhalants is not related to peroxynitrite formation. Toxicology Letters 132: 37-45.
118. Soderberg, L. et al., 2002. The abused inhalant, isobutyl nitrite, is cytotoxic by means other than peroxynitrite formation. Drug and Alcohol Dependence Abstract #629. S2-202: S168.
119. Soderberg, L. et al., 2000. Nitrite inhalants spontaneously liberate nitric oxide, which is not responsible for the immunotoxicity in C57BL/6 mice. International Journal of Immunopharmacology 22: 151-157.
120. Akerboom, Theodorus et al., 1997. Subunit specificity and organ distribution of glutathione transferase-catalysed S-Nitrosoglutathione formation from alkyl nitrites in the rat. Biochemical Pharmacology 53:117-120.

Prevalence of use

121. Sullivan, Patrick et al., 1998. Geographic differences in noninjection and injection substance use among hiv-seropositive men who have sex with men: Western United States versus other regions. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology 19:266-273.
122. Skinner, William et al., 1996. Drug and alcohol use among lesbian and gay people in a southern U.S. sample: Epidemiological, comparative, and methodological findings from the Trilogy Project. Journal of Homosexuality 30(3): 59-91.
123. Lange, W. Robert et al., 1988. Nitrite Inhalants: Patterns of abuse in Baltimore and Washington, D.C. American Journal of Drug and Alcohol Abuse 14(1): 29-39.
124. Williford Pifer, Linda et al., 1987. Borderline Immunodeficiency in male homosexuals: Is life-style contributory? Southern Medical Journal 80(6): 687-691-7.

Overview articles showing why poppers use is hazardous and needs to be discouraged

125. Haverkos, Harry et al., 1994. Nitrite Inhalants: History, Epidemiology, and Possible Links to AIDS. Environmental Health Perspectives 102(10): 858-861.
126. Wilson, Hank., 1999, March. The poppers-HIV connection. Focus 14(4): 5-6.

Risk factor for Kaposi's Sarcoma

127. Haverkos, Harry et al., 2002. Letter to editor re: Relationship between Kaposi Sarcoma-associated herpesvirus and HIV. JAMA 287(12): 1525-1528 responding to the article: Osmond, Dennis et al., 2002. Prevalence of Kaposi Sarcoma-associated herpesvirus infection in homosexual men at the beginning of and during the hiv epidemic. JAMA 287(2): 221-225.

128. Drotman, Peter et al., Kaposi's Sarcoma: How can epidemiology help find the cause? JAMA 13(3): 575-582.

Example that is compelling because the sales ad endangers consumers:

www.epoppers.com features both poppers and VIAGRA prominently in the website. Both poppers and VIAGRA are featured at the top of the website. Besides prominent location, the size and style of lettering are prominent and adjacent with NO CAUTIONARY warnings. This endangers consumers. This particular site selling poppers includes selling amyl nitrite poppers. FDA is aware of the lethal combination of poppers and VIAGRA. Action against these blatantly endangering websites is overdue.

Enforcement action in this blatant case seems obvious if FDA gives any value to protecting gay consumers. The impact of the AIDS epidemic effects everyone, because everyone pays for the costs of caring and dealing with morbidity in the AIDS epidemic. And it is in this AIDS epidemic context that we are petitioning for FDA to enforce the law and protect consumers.

action, with penalties, will have both an education effect on unaware consumers and as well as a deterrent effect on those sellers who violate the laws. Both effects are desirable and can be achieved with minimal resources, but with wide ranging and long lasting impacts.

Enforcement action involves many options. FDA might start serving notice on violators. And publicize the giving of notice. Such publicity will serve as an alert to consumers. There is precedent for issuing alerts.

Sincerely,



Hank Wilson

Committee to Monitor Poppers/SURVIVE AIDS